

about rapid absorption if you mix it with even small amounts of alcohol, but the available studies are only abstracts and/or cancer patients so they don't meet inclusion criteria anyway.

Next slide. So just to summarize the update on long-acting opioids for non-cancer pain. There's only five head-to-head trials. One is rated fair quality. They found that the drugs that were compared were similar for efficacy and there were some mixed results for safety adverse events. In particular a transdermal fentanyl in some studies appears to be associated with a lower risk of constipation although not for a lower risk of overall adverse events or withdrawal due to adverse events. We await trials of long-acting hydromorphone although currently it's not available in the U.S. There's only one trial of levorphenol and one placebo-controlled trial of methadone. Both in patients with neuropathic pain and again as mentioned before those results aren't comparable to other studies because of issues with design. There's generally poor adverse event assessment quality in these qualities and there's no evidence that one long-acting opioid is superior to others or that long-acting opioids as a class are superior to short-acting. There's also no data on comparative risk of addiction or abuse.

I think that's it. So if there are any questions.

Carol Cordy: Thank you, Roger, that was excellent. Is there...are there any questions from the committee? Roger, can you stay a few minutes if there's some discussion after the stakeholders?

Roger Childs: Yeah, I'm happy to.

Carol Cordy: Okay. We have two stakeholders. Is there anyone besides Dr. Dermot Fitzgibbon and Carrie Aaron that didn't get your name on here? Okay. Dr. Fitzgibbon? And if you could say who you're representing and if you're representing any pharmaceutical company.

Dermot Fitzgibbon: I'm not representing a pharmaceutical company. My name is Dermot Fitzgibbon. I'm a physician at the University of Washington's Seattle Cancer Care Alliance. I really have no invested interest in any particular opioid, but I have a vested interest in using opioids for cancer patients and my biggest concern is that if we restrict opioid use to two types—extended release morphine and methadone, this is going to be a real problem for the long-term management of many of the patients that I see.

Many of the patients that I see are cancer patients, but the cancer patients that I see typically have chronic problems and when we prescribe opioids for these patients we expect these patients to be on opioids for a long time. The data that I have seen regarding methadone use, I think is particularly problematic. I have seen situations where conversions from various long-acting opioids to methadone are inappropriate and the doses are too high. I would strongly recommend to the committee that we keep open the large variety of long-acting opioids that are currently on the market and I would ask you not to restrict medication use to the two kinds(?) proposed.

Carol Cordy: Thank you.

Jeff Graham: This is Jeff Graham. I just wanted to comment to you that all cancer patients are excluded from this study and that cancer patients can receive any of the long-acting opioids.

Dermot Fitzgibbon: If I may answer that. We have not been seeing that in our practice. We have found increasingly that there are restrictions placed on oncology patients who have a diagnosis of chronic pain and the tendencies that we've been seeing recently is that if you do not have a diagnosis of tumor-associated pain there are increasing restrictions from a variety of different sources in our prescription practices.